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EXAMINER

ALEXANDER, LYLE

ART UNIT PAPER NUMBER

1743

DATE MAILED: 03/21/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/805,653

Applicant(s)

BUECHLER, KENNETH F.

Examiner

Lyle A Alexander

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74, 75 and 77-100 is/are rejected.
- 7) ☒ Claim(s) 76 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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In response to the 1/10/03 Appeal Brief the search was updated and pertinent new references were discovered. The Office has withdrawn the finality of the 6/24/02 office action in favor of the new grounds of rejection below. Further, in light of re-opening the prosecution, the Office has entered the 9/30/02 amendments after final amendments.

Claim Rejections - 35 USC § 112

Claims 75, 90 and 96 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The original specification teaches "at least one target ligand". There does not appear to be any teaching of the claimed "at least 50 said discrete capture zones".

Claims 78, 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 78 is not clear what structure is intended by the claimed "time gate". For the purposes of examination it will be assumed a time gate is any absorbent structure capable of influencing the rate of flow.

Claim 82 is not clear what is intended by a "nanoparticle". For the purposes of examination it will be assumed a the claimed nanoparticle is a small particle .

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 74,77,79-88 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21,1-44, 1-50 and 1-15 of U.S. Patent No. 6,143,576; 6,156,270 ; 6,019,944 and 5,458,852 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a diagnostic device capable of capturing "at least one target ligand".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 74,77-84,86,88-89,91-93,95 and 97-100 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sun et al.(USP 5,238,652).

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Sun et al. teach an assay device for the simultaneous determination of multiple analytes. In column 2 lines 48+, Sun et al. teaches simultaneous of 5 common drugs of abuse. This has been read on the claimed plurality of different target ligands. Column 4 teaches the latex particles sensitized with antibodies which has been read on the claimed capture element. Column 6 teaches the latex spheres can be 0.1 micron which has been read on the claimed 100 nanometers. Sun et al. teach in column 6 colored lines across the membrane which have been read on the claimed a "width dimension substantially perpendicular to the direction of flow ... where each capture zone spans the width". In the absence of better defining what structure is intended by a "time gate" the Office has read the passage(108) which delays the sample on the claimed time gate. Sun et al. teach in column 5 lines 40-41 impregnation of antigen which has been read on the claimed "entrapment".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 78,85,87 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al.

See Sun et al. *supra*.

Sun et al. is silent to covalent bonding, the claimed size range of 0.1-10 mm and use of a fluorescent label.

The court decided In re Boesch (205 USPQ 215) the optimization of a result effective variable is ordinarily within the skill of the art. The selection of a covalent binding, the size range of the particle and use of a fluorescent label are all result effective variables.

Covalent binding of immunogens to a particle is well known. Covalent bonds have the advantage of being very strong. It would have been within the skill of the art to modify Sun et al. and use a covalent bond as selection of a result effective variable and to gain the above advantages.

Selection of larger particles would have been advantageous to make a more vivid display. . It would have been within the skill of the art to modify Sun et al. and use 0.1-10 mm particles as selection of a result effective variable and to gain the above advantages.

Fluorescent labels have the advantage of being very visible and can be quantitatively analyzed. . It would have been within the skill of the art to modify Sun et al. and use a fluorescent label as selection of a result effective variable and to gain the above advantages.

Allowable Subject Matter

Claim 76 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 74-100 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 703-308-3893. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9319 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.



Lyle A Alexander
Primary Examiner
Art Unit 1743

March 19, 2003



Jill Warden
Supervisory Patent Examiner
Technology Center 1700